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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,584	04/27/2006	Mark Jensen	21568P	7482
210 7590 04/28/2008 MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907				
EXAMINER				
AULAKH, CHARANJIT				
ART UNIT		PAPER NUMBER		
1625				
MAIL DATE		DELIVERY MODE		
04/28/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/577,584

Applicant(s)

JENSEN ET AL.

Examiner

Charanjit S. Aulakh

Art Unit

1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. According to paper filed on Jan. 14, 2008, the applicants have amended claims 1-5.

The applicants have also submitted a new abstract.

2. Claims 1-5 are pending in the application.

Response to Arguments

3. Applicant's arguments filed on Jan. 14, 2008 have been fully considered but they are not persuasive regarding enablement rejection of claims 3 and 4; prior art rejection, obviousness rejection and ODP rejection. In regard to enablement rejection, the examiner does not agree with the applicants arguments that the WO 03/093266 clearly teaches the utility of instant compounds for treating every known inflammatory and immunoregulatory disease. This publication broadly mentions the use of CCR-2 receptor modulators for treating these disorders without any specific evidence. the term --- modulating-- encompasses both agonists and antagonists of CCR-2 receptors and therefore, both agonists and antagonists can not have the identical utility. The applicants need to provide prior art references showing well established utility of CCR-2 receptor antagonists for treating every known inflammatory and immunoregulatory disorders including rheumatoid arthritis or provide references showing efficacy of CCR-2 receptor antagonists in known animal models of every known inflammatory and immunoregulatory disorder including rheumatoid arthritis.

In regard to prior art rejection, the examiner does not agree with the applicants arguments that the cited patent does not disclose the specific succinate salt claimed in the present application. Actually, succinate salt is claimed in claim 29 of this patent. In regard to obviousness rejection, the examiner does not agree with the applicants arguments that Jiao does not suggest specific salt. Jiao does teach specific salts including succinate salt as well as methods of preparing these salts on page 5. Preparation of salts of a known compound is not a specialized field and is within the

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routine skill of an artisan. The therapeutic utility or inhibition of CCR-2 receptor activity is due to the compound itself and is not the property of any specific salt of the compound. The applicants have not provided any evidence of any specific special property of succinic salt of this compound as compared to the compound itself or other salts.

In regard to ODP rejection, the applicants mention that they will consider filing a TD.

Conclusion

4. Rejection of claims 3 and 4 under 35 U.S.C. 112, first paragraph is maintained for the reasons of record.

5. Rejection of claims 1-5 under 35 U.S.C. 102(e) is maintained for the reasons of record.

6. Rejection of claims 1-5 under 35 U.S.C. 103(a) is maintained for the reasons of record.

7. The provisional ODP rejection of claims 1 and 5 is maintained for the reasons of record.

8. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571)272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charanjit S. Aulakh/
Primary Examiner, Art Unit 1625

